

## REMARKS

Claims 126-128, 132-138 and 165-167 are currently pending in the above-identified application. Claims 129-131 and 139-164 have been canceled without prejudice. New claims 165-167 have been added. Claims 126 and 132-135 have been amended. Support for the amendment to claim 126 can be found on page 15, paragraph [52], Example 1 on pages 14-15, and Figure 1 of the specification as originally filed. No new matter has been added.

The claim amendments and cancellations should not be construed to be an acquiescence to any of the claim rejections. Rather, the amendments and cancellations are being made solely to claim more clearly the invention and to expedite the prosecution of the above-identified application. The Applicant reserves the right to further prosecute the same or similar claims in subsequent patent applications claiming the benefit of priority to this application. 35 U.S.C. § 120.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

### Claim Objections

Claim 139 is objected to for allegedly reciting grammatically awkward language. The Applicants have canceled claim 139 without prejudice.

Claims 127 and 128 are objected to under 37 CFR 1.175(c) as being of improper dependent form. The Applicants have amended claim 126 to clarify the identities of the zinc-containing components.

Claims 140 and 141 are objected to under 37 CFR 1.175(c) as being of improper dependent form. The Applicants have canceled claims 140 and 141 without prejudice.

Claims 153 and 154 are objected to under 37 CFR 1.175(c) as being of improper dependent form. The Applicants have canceled claims 153 and 154 without prejudice.

Claim 152 is objected to for reciting an improper Markush construction. The Applicants have canceled claim 152 without prejudice.

Accordingly, the Applicants respectfully request reconsideration and withdrawal of the claim objections.

**Rejections Based on 35 U.S.C. § 112**

*Claims 126-164*

Claims 126-164 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. The Applicants respectfully traverse.

Claims 129-131 and 139-164 have been canceled. As to the remaining claims, the Applicants has amended claim 126 to include the limitation that zinc is present at a concentration in the range of about 10  $\mu$ M to about 1 mM. Support for this amendment can be found on page 15, paragraph [52] and Figure 1 of the specification as originally filed.

Applicants respectfully assert that the amended claims wholly comply with the written description requirement based on the disclosure found on page 15 of the specification and Figure 1. The Applicants have shown that while high doses of zinc (in the form of the zinc component zinc acetate) in the vicinity of 100 mM caused epidermal sloughing and irritation of the skin, lower doses of zinc (e.g., about 10  $\mu$ M and about 1 mM) afforded the benefits of increased elastin content in the skin without detrimental effects.

Furthermore, the Applicants respectfully disagree with the Examiner that the disclosure does not “clearly attribute the ‘epidermal sloughing and irritation’ directly and specifically to the zinc component.” The Applicants point the Examiner to Example 1, where the Applicants have shown that the only change to the topical formulation applied to the skin was increasing the concentration of the zinc component. Based on this information, the skilled artisan would infer that the zinc component was the cause of the observed epidermal sloughing and irritation. Importantly, epidermal sloughing and irritation is shown only when zinc is present in the high-concentration formulation (i.e., 100 mM).

Based on the foregoing, the Applicants respectfully contend that the amended claims comply with the written description requirement.

*Claims 126-128, 135-141, 148-154 and 161-164*

Claims 126-128, 135-141, 148-154 and 161-164 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. The Applicants respectfully traverse.

Claims 139-141, 148-154 and 161-164 have been canceled. As to the remaining claims, the Applicants have amended claim 126 to include the limitation that zinc is present at a concentration in the range of about 10  $\mu\text{M}$  to about 1 mM. Support for this amendment can be found on page 15, paragraph [52] and Figure 1 of the specification as originally filed. Thus, the Applicants respectfully contend that the amended claims comply with the written description requirement.

Accordingly, the Applicants respectfully request withdrawal of the claim rejections based on 35 U.S.C. § 112, first paragraph.

**Rejections Based on 35 U.S.C. § 112**

*Claims 126-164*

Claims 126-164 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 129-131 and 139-164 have been canceled. As to the remaining claims, the Applicants respectfully contend that there is no ambiguity with respect to the limitations as to concentration because the formula of each recited zinc salt contains a single zinc dication ( $\text{Zn}^{++}$ ). Consequently, the molar concentrations of the zinc salt and the zinc dication are identical values for a given formulation.

*Claims 126-138 and 152-164*

Claims 126-138 and 152-164 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 152-164 have been canceled. As to the remaining claims, the Applicants have amended claim 126 to specify that the concentration of the one or more zinc-containing components is in the range of about 10  $\mu$ M to about 1 mM.

*Claims 126, 129, 132, 135, 136, 138, 139, 142, 145, 149, 152, 155, 158, 161, 162 and 164*

Claims 126, 129, 132, 135, 136, 138, 139, 142, 145, 149, 152, 155, 158, 161, 162 and 164 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 129, 139, 142, 145, 149, 152, 155, 158, 161, 162 and 164 have been canceled. As to the remaining claims, the Applicants have amended claim 126 to add the term “zinc” before the name of each of the remaining anionic components.

*Claims 135 and 148*

Claims 135 and 148 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 148 has been canceled. The Applicants have amended claim 135 remove the phrase “and the composition is applied to a site on the skin of the subject” to remove any redundancy with claim 126, from which claim 135 depends.

Lastly, the Applicants wish respectfully to remind the Examiner that the Office’s official position, as reflected in the MPEP, is that absolute precision and clarity are not required to comply with the requirements of 35 USC 112¶ 2. *See MPEP* § 2173.02 (excerpt reproduced below).

The examiner’s focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. When

the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. Examiners are encouraged to suggest claim language to applicants to improve the clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement. *MPEP* § 2173.02.

Accordingly, the Applicants respectfully request withdrawal of the claim rejections based on 35 U.S.C. § 112, second paragraph.

**Rejections Based on 35 U.S.C. § 103(a)**

Claims 126, 128-131, 135-139, 141-144, 148-150, 152, 154-157, and 161-164 stand rejected under 35 U.S.C. § 103 as being unpatentable over Petrus (U.S. Patent No. 6,573,299) in view of Uitto (Dermatol. Clin. 4(3): 433-436 (1986)). The Applicants respectfully traverse.

To establish a *prima facie* case of obviousness, a number of criteria must be met. For example, all of the limitations of a rejected claim must be taught or suggested in the prior art reference (or references when combined) relied upon by the Examiner; or they must be among the variations that would have been “obvious to try” to one of ordinary skill in the relevant art in light of the cited reference(s). Moreover, one of ordinary skill in the relevant art must have a reasonable expectation of success in light of the cited reference or combination of references. Importantly, the reasonable expectation of success must be found in the prior art, and may not be based on the Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991); *see* *MPEP* § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Claims 129-131 and 139, 141-144, 148-150, 152, 154-157, and 161-164 have been canceled. As to the remaining claims, the Applicants believe that the Examiner has failed to state a *prima facie* case of obviousness for the rejected claims, as the cited reference does not teach or render “obvious to try” each and every element of the amended claims.

Amended claim 126 provides for:

A method of increasing elastin content in a region of the skin of a subject, comprising applying topically a composition consisting essentially of one or more zinc-containing components in admixture with a dermatologically or pharmaceutically acceptable carrier, in an elastin-increasing effective amount, to the region of skin of the subject, where the one or more zinc-containing components is selected from the group consisting of zinc acetate, zinc ascorbate, zinc aspartate, zinc butyrate, zinc caproate, zinc caprylate, zinc carbonate, zinc citraconate, zinc citramalate, zinc citrate, zinc EDTA, zinc formate, zinc fumarate, zinc gallate, zinc gluconate, zinc halides, zinc lactate,  $\gamma$  zinc malate, zinc maleate, zinc malonate, zinc metaphosphate, zinc monophosphate, zinc nitrate, zinc octoate, zinc orotate, zinc orthophosphate, zinc oxalate, zinc phosphate, zinc picolinate, zinc propionate, zinc pyrophosphate, zinc salicylate, zinc selenate, zinc succinate, zinc sulfate, zinc sulfonate, zinc tartrate, zinc tetrametaphosphate, zinc tripolyphosphate, zinc valerate, zinc amino acid complexes, zinc nucleotide complexes, and mixtures thereof, where the one or more zinc-containing components is present in the composition at a concentration that increases elastin without causing epidermal sloughing and irritation due to zinc, where said concentration is in the range of about 10  $\mu$ M to about 1 mM, and where the elastin content in the region of skin is increased in a sufficient amount to treat wrinkles.

The combination of cited references fails to teach or render obvious to try all of the limitations of the amended claims.

Furthermore, one of ordinary skill in the art would not have had a reasonable expectation of success in developing the claimed methods based on the cited combination of references. For instance, Petrus discloses a long list of possible ingredients for inclusion in the topical compositions used in their methods, which includes “zinc compounds”. Based on the combination of references, one of skill in the art would be presented with an infinite number of options to choose from, but no direction as to how to arrive at the Applicants’ claimed methods. Critically, the process of selecting and experimentally validating specific subgenuses and species within the generic disclosure of the combination of cited references is just the sort of inventive effort that the patent system is designed to encourage, and that should be rewarded with a patent. In fact, Applicant submits that without the

benefit of Applicant's invention as a road map one of ordinary skill in the art would not have arrived at the claimed invention. The mere fact that one could explore and vary a number of possible variables to arrive at the particular limitations now claimed does not establish obviousness because there would have been no reasonable expectation that the particular combination of limitations now claimed would be preferred over any other combination. In support of this reasoning, the Federal Circuit has held that "in cases involving new compositions of matter, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound." *Takeda v. Alphapharm*, 492 F.3d 1350 (Fed. Cir. 2007).

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 103(a).

#### **Copending Applications**

The Applicants note the Examiner's request to provide a list of copending U.S. applications that set forth similar subject matter to the present claims and share an inventor or assignee with the instant application. The Applicants point the Examiner to U.S. Patent Application No. 10/692,474, filed on October 22, 2003, now abandoned.

**FEES**

The Applicants believe they have provided the required fee in connection with the filing of this paper. Nevertheless, the Director is hereby authorized to charge any additional required fees to our **Deposit Account No. 06-1448, reference PDX-018.01.**

**CONCLUSION**

In light of the foregoing remarks, Applicant respectfully submits that the pending claims are in condition for allowance. Reconsideration and timely allowance of the pending claims is respectfully solicited. If a telephone interview would be helpful, the Examiner is invited to call the undersigned at 617-832-1000.

Dated: October 20, 2011

Respectfully submitted,

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